MPC
MEDICAL PHYSICS
CONSULTANTS, INC.

July 16, 2014

Randy D. Hicks, M.D.
Radiation Safety Officer
REGIONAL MEDICAL IMAGING
3346 Lennon Rd.
Flint, MI 48532

RE: Authorized User Amendment

Dear Jill:

Enclosed please find the letter to the NRC for the addition of Dr. Youssef as an authorized user to your NRC license. The following steps need to be taken for completion.

1. Please carefully review the entire response, including **names, license number, and addresses** that all information is correct. Copy the cover letter to the state onto facility letterhead.

2. Have executive management sign the letter to the NRC.

3. Make a copy of all documents (including preceptor forms and board certification letter). These will go to the NRC. **Keep the original and file in the blue, MPC, license binder in the nuclear medicine department**.

4. Mail the signed copies to the following address: **Federal Express or U.P.S. is advised.**

United States Nuclear Regulatory Commission
Region III, Materials Licensing
2443 Warrenville Road, Ste 210
Lisle, IL 60532-4352

If you have any questions, please contact me at (734) 662-3197.

Sincerely,

Laura M. Luna

Laura M. Luna, B.S.
Physics Consultant
Enclosures

RECEIVED JUL 2 9 2014

2309 Shelby Avenue
Ann Arbor, MI 48103
(734) 662-9224 Fax
(734) 662-3197

70 E. 91st Street, Suite 106
Indianapolis, IN 46240
(317) 581-1931 Fax
(317) 581-1911

4806 Mile High Drive
Salt Lake City, UT 84124
(801) 272-2952 Office & Fax

N7375 Crystal Ridge Drive
Beaver Dam, WI 53916
(920) 885-9872 Fax
(920) 885-9870

www.mpcphysics.com

REGIONAL MEDICAL IMAGING

Main Office
3346 Lennon Road | **Flint**, MI 48507
810.732.1919 PHONE | 810.732.1945 FAX
Flint ■ Fenton ■ Grand Blanc ■ Villa Linde ■ Davison
www.rmipc.net

July 24, 2014

United States Nuclear Regulatory Commission
Region III, Materials Licensing
2443 Warrenville Road, Ste 210
Lisle, IL 60532-4352

Re: Amendment to License #21-26076-01

Please amend our license to reflect the following changes:

1. Please add Dr. Ehab Hassan A. Youssef, M.D. to our license as an authorized user for 10 CFR 35.100, 35.200, and 35.300.

   Please find a copy of his Board Certification letter and preceptor forms, for both diagnostic and therapy use, enclosed.

Thank you for your cooperation with this matter. If you have any questions or require additional information please contact our physics consultant, Laura Luna, at (734) 662-3197.

Sincerely,

Randy Hicks, M.D.
Executive Administration, Radiation Safety Officer

THE AMERICAN BOARD OF RADIOLOGY

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May 30, 2014

Diagnostic Radiology
ABR ID: 66628

Ehab Hassan Abdel Rahman Youssef, MBBCh
Department of Radiology, UH B1 D520
University of Michigan
1500 E Medical Center Drive
Ann Arbor, MI 48109

Dear Dr. Youssef:

I am pleased to inform you that you passed the Oral Examination held May 18 - 20, 2014 in Louisville, Kentucky. Because your four-year program ends after June 30, 2014, the American Board of Radiology will grant you a Certificate in Diagnostic Radiology when the ABR has received verification of your completed program.

In addition, because you completed the appropriate training for Authorized User (AU) eligibility and passed the NRC-related portions of the nuclear radiology category, you will receive the AU-eligible designation on your certificate.

All new diplomates are enrolled in Continuous Certification, a process that links the ongoing validity of certificates to meeting the requirements of Maintenance of Certification (MOC). Certificates no longer have "valid-through" dates but instead have the date of initial certification accompanied by the statement that "ongoing validity of this certificate is contingent upon meeting the requirements of Maintenance of Certification." Further information regarding the MOC process will be provided to you in a separate communication.

When you become certified, you may use the ABR's registered certification mark, DABR (Diplomate, American Board of Radiology), following your name and degree. (More information can be found on the policies page of the ABR website: http://www.theabr.org/all-policies.)

Our printer will send your certificate to the above address approximately four months after you become certified. If you have an address change, you must update your address via your myABR portal by June 30, 2014. Your name will appear on the certificate as it is shown above. If you wish to have your name displayed differently on your certificate, please email info@theabr.org with your requested change by June 30, 2014. Please be sure to title the email "Certificate Name Change." Legal name changes cannot be made via your myABR portal as they require supporting documentation, which can be emailed to info@theabr.org.

Your name and demographic information also will be included in a directory published by the American Board of Medical Specialties. It is your responsibility to notify other local, state, or national organizations of your certification.

Personally, and on behalf of the Board of Trustees of the American Board of Radiology, I wish to congratulate you for this distinguished achievement.

Sincerely,

NRC FORM 313A (AUD)
(05-2012)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: (05/31/2015)

Name of Proposed Authorized User	State or Territory Where Licensed
Ehab Hassan A. Youssef	Michigan

Requested Authorization(s) *(check all that apply)*

- [✓] 35.100 Uptake, dilution, and excretion studies
- [✓] 35.200 Imaging and localization studies
- [ ] 35.500 Sealed sources for diagnosis (specify device) _____

PART I -- TRAINING AND EXPERIENCE

(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

[✓] **1. Board Certification**

a. Provide a copy of the board certification.

b. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.

[ ] **2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization**

a. Authorized user on Materials License _____ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.

b. Supervised Work Experience.
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			
Total Hours of Experience:			

Supervising Individual	License/Permit Number listing supervising individual as an authorized user

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check all that apply).*

[ ] 35.290 [ ] 35.390 + generator experience in 32.290(c)(1)(ii)(G)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

☐ **3. Training and Experience for Proposed Authorized User**

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use *(not required for 35.590)*			
Radiation biology			
Total Hours of Training:			

b. Supervised Work Experience (completion of this table is not required for 35.590).
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervised Work Experience — **Total Hours of Experience:**

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		☐ Yes ☐ No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		☐ Yes ☐ No	

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience. (continued)

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes ☐ No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		☐ Yes ☐ No	
Administering dosages of radioactive drugs to patients or human research subjects		☐ Yes ☐ No	
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs		☐ Yes ☐ No	

Supervising Individual	License/Permit Number listing supervising individual as an authorized user

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check one)*.

☐ 35.190 ☐ 35.290 ☐ 35.390 ☐ 35.390 + generator experience in 35.290(c)(1)(ii)(G)

c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35.590)

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section
Check one of the following for each use requested:

For 35.190

Board Certification

☑ I attest that Ehab Hassan A. Youssef has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

☑ I attest that Ehab Hassan A. Youssef has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

Second Section
Complete the following for preceptor attestation and signature:

☑ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☑ 35.190 ☑ 35.290 ☐ 35.390 ☐ 35.390 + generator experience

Name of Preceptor	Signature	Telephone Number	Date
Kirk A. Frey, M.D., Ph.D.		(734) 936-5388	06/17/2014

License/Permit Number/Facility Name
University of Michigan 21-00215-04

NRC FORM 313A (AUT) (05-2012) | U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: (05/31/2015)

Name of Proposed Authorized User	State or Territory Where Licensed
Ehab Hassan A. Youssef	Michigan

Requested Authorization(s) *(check all that apply)*:

☑ 35.300 Use of unsealed byproduct material for which a written directive is required

OR

☐ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ 35.300 Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ 35.300 Parenteral administration of any other radionuclide for which a written directive is required

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☑ **1. Board Certification**

a. Provide a copy of the board certification.

b. For 35.390, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience.

c. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience.

d. Skip to and complete Part II Preceptor Attestation.

☐ **2. Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization**

a. Authorized User on Materials License _____ under the requirements below or equivalent Agreement State requirements *(check all that apply)*:

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.490 ☐ 35.690

b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

☐ **3. Training and Experience for Proposed Authorized User**

a. Classroom and Laboratory Training ☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use			
Radiation biology			
	Total Hours of Training: ☐		

b. Supervised Work Experience ☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Supervised Work Experience	**Total Hours of Experience:**		
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		☐ Yes ☐ No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		☐ Yes ☐ No	
Calculating, measuring, and safely preparing patient or human research subject dosages		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes ☐ No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		☐ Yes ☐ No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:*

☐ 35.390
☐ 35.392
☐ 35.394
☐ 35.396

With experience administering dosages of:

☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
☐ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. Supervised Clinical Case Experience
If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	16	University of Michigan 21-00215-04	07-01-2011 thru 06-30-2013
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	14	University of Michigan 21-00215-04	07-01-2011 thru 06-30-2013
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required	8	University of Michigan 21-00215-04	07-01-2011 thru 06-30-2013
Parenteral administration of any other radionuclide for which a written directive is required (List radionuclides)	0	University of Michigan 21-00215-04	07-01-2011 thru 06-30-2013

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Case Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:*

☑ 35.390	With experience administering dosages of:
☑ 35.392	☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
☑ 35.394	☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
☐ 35.396	☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
	☐ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

d. Provide completed Part II Preceptor Attestation.

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section
Check one of the following for each requested authorization:

For 35.390:

Board Certification

☑ I attest that Ehab Hassan A. Youssef has satisfactorily completed the training and experience
Name of Proposed Authorized User

requirements in 35.390(a)(1).

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

☐ I attest that _____ is an authorized user under 10 CFR 35.490 or 35.690
Name of Proposed Authorized User

or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required

OR

Board Certification:

☐ I attest that _____ has satisfactorily completed the board certification
Name of Proposed Authorized User

requirements of 35.396(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required

Fifth Section
Complete the following for preceptor attestation and signature:

☑ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☑ 35.390 ☑ 35.392 ☑ 35.394 ☐ 35.396

☑ I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☑ Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor	Signature	Telephone Number	Date
Kirk A. Frey, M.D., Ph.D.		(734) 936-5388	06/17/2014

License/Permit Number/Facility Name
University of Michigan 21-00215-04

LTR 1 OF 1

FROM:
JILL SEROUM
(810) 732-1846
REGIONAL MEDICAL IMAGING
3346 LENNON RD.
FLINT MI 48507-1082

SHIP TO:

U.S NUCLEAR REGULATORY COMMISSION
2443 WARRENVILLE RD STE 210
REGION LLL,MATERIALS LICENSING
LISLE IL 60532-4352

IL 603 9-03

UPS NEXT DAY AIR SAVER **1P**
TRACKING #: 1Z 7V9 R81 13 6763 6685

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WS 16.0.31 51.0A 04/2014

Fold here and place in label pouch